K091245
182

510(k) SUMMARY

SUBMITTER INFORMATION

JUN 17 2009

A. Company Name: Preservation Solutions Inc.

B. Company Address: 980 Proctor Drive
Elkhorn, Wisconsin 53121

C. Company Phone: 262 723 6715

D. Company Facsimile: 262 723 4013

E. Contact Person: William Wagner
Quality Assurance Director

DEVICE IDENTIFICATION

A. Device Trade Name: CoStorSol®

B. Device Common Name: Organ Storage Solution

C. Classification Name: Isolated kidney perfusion and transport system and accessories

D. Class II (21 CRF 876.5880)

E. Device Code: KDN

IDENTIFICATION OF PREDICATE DEVICES

CoStorSol®, to be stored at ambient room temperature, is a transplant graft storage solution for harvested organs, which is substantially equivalent to the original CoStorSol® solution cleared to market under premarket notifications K073693 and K083453.

DEVICE DESCRIPTION

Preservation Solutions, Inc. manufacturers CoStorSol® according to a "recipe" pioneered at the University of Wisconsin by Folkert O. Belzer, MD and James H. Southard, PhD. Indeed, the cold storage solution is often referred to as "Belzer UW" solution. The formulation includes soluble colloids, buffers, sodium and potassium salts, redox stabilizers, and phosphoric compounds to aid tissue viability by enabling regeneration of adenosine triphosphate (ATP).

CoStorSol® is a clear to light yellow, sterile, non-pyrogenic solution for hypothermic flushing and storage of organs. The solution is packaged in 1-liter bags, which must be chilled to between 2° and 6° C prior to use. The solution may be used without any point of use filtration.

INDICATIONS FOR USE

CoStorSol® is intended for the flushing and cold storage of kidney, liver and pancreas organs at the time of organ removal from the donor in preparation for storage, transportation and eventual transplantation into a recipient.

COMPARISON TO PREDICATE DEVICES

CoStorSol® solution was cleared under 510(k) K083453 with a specified shelf life of one (1) year when stored under refrigeration at temperatures no lower than 2°C, or at ambient indoor temperatures up to 25°C. There has been no change in the formulation, packaging, or indication for use for the product. The proposed CoStorSol® solution is identical to the predicate, but label instructions to pass the solution though a microfilter (Pall Blood Transfusion Filter) at the time of use have been removed. Preservation Solutions, Inc. has compiled data showing that unfiltered CoStorSol® is equivalent to filtered CoStorSol®. The directions to chill CoStorSol®, prior to its use for flushing or storing organs for transplant, remain unaltered. Only the instruction to connect a sterile microfilter to the spike port while draining the solution from its flexible container has been deleted from the labeling. The solution was, and is still designed for storage without freezing. CoStorSol® will continue to be supplied in 1-liter flexible bags for connection to standard administration sets for flushing of harvested organs. CoStorSol® is used as an initial vasculature flush medium for an organ, and then as a cold storage medium.

BIOCOMPATIBILITY, STERILIZATION, PACKAGING, AND BENCH TESTING

Test results have shown CoStorSol® itself to be a biocompatible solution, supplied in flexible solution administration pouches, which have likewise been tested and shown to be biocompatible. The ISO 10993 series of standards were referenced during the planning and execution of all biocompatibility testing. Particulate matter does not exceed the limits set in USP Section <788>, for large volume injections. CoStorSol® is supplied sterile and non-pyrogenic in order to assure safety for transplant recipients. Sterilization processes were validated according to either ISO 17665 or USP Section <1211>, as appropriate.

CONCLUSION

The above statements establish substantial equivalence between the predicate, CoStorSol® with instructions to pass the solution through a microfilter at the time of use, and the proposed product, CoStorSol® without instructions for final filtration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2009

Preservations Solutions, Inc.
% Mr. Neil Burris
Principal
Neil Burris and Associates
4250 Grove Street
DENVER CO 80211

Re: K091245
Trade/Device Name: CoStorSol®
Regulation Number: 21 CFR 876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: II
Product Code: KDN
Dated: April 20, 2009
Received: April 28, 2009

Dear Mr. Burris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091245
1 of 1

5. Statement of Indication for Use

Device Name: CoStorSol®

Indications for Use

CoStorSol® is intended for the flushing and cold storage of kidney, liver and pancreas organs at the time of organ removal from the donor in preparation for storage, transportation and eventual transplantation into a recipient.

Prescription Use **XXXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K091245